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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------------|------------------|
| 10/003,468  | 10/23/2001  | Fatemeh Mojtabei     | FMI-001                       | 4328             |
| 959 7590 04/19/2007<br>LAHIVE & COCKFIELD, LLP<br>ONE POST OFFICE SQUARE<br>BOSTON, MA 02109-2127 |             |                      | EXAMINER<br>MORAN, MARJORIE A |                  |
|   |             |                      | ART UNIT                      | PAPER NUMBER     |
|   |             |                      | 1631                          |                  |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 04/19/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/003,468

Applicant(s)

MOJTABAI, FATEMEH

Examiner

Marjorie Moran

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 3-6, 8, 63, 64 and 67-73 is/are pending in the application.
- 4a) Of the above claim(s) 72 and 73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-6, 8, 63, 64, and 67-71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/23/07 has been entered.

Claims 1, 3-6, 8, 63, 64, and 67-73 are pending. The rejections made under 35 USC 112 are hereby withdrawn in view of the amendment filed 1/23/07.

***Election/Restrictions***

Claims 72 and 73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/3/05. In the response filed 1/3/05, applicant elected species of membrane protein, gas-aqueous interface, and proteoliposomes. The species of orphan receptors and water insoluble proteins, as recited in new claims 72 and 73 were not elected. It is noted that water insoluble proteins were not recited in the original claims. Many membrane proteins are soluble in aqueous (water) solutions, depending on the buffer, salts, pH, etc. of the solution, therefore water insoluble proteins are considered a distinct and different species from that of membrane proteins. Thus, claims 72 and 73 are directed to nonelected species, and are withdrawn.

An action on the merits of claims 1, 3-6, 8, 63, 64, and 67-71, as they read on the elected species of membrane protein, proteoliposome, and gas-aqueous interface, follows.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Claims 1, 3-5, 8, 64, and 67-70 are rejected under 35 U.S.C. 102(b) as being anticipated by RIBI (US 4859538).

RIBI teaches a method of constructing 2 and 3 dimensional ordered (crystalline) arrays of proteins by contacting an air-water interface with a lipid composition comprising a protein, and allowing the mixture to incubate under spreading (i.e. lateral) pressure until the crystals (array) form (see examples at 9, line 62-col. 10, line 39, col. 11, line 55-col. 12, line 8, and col. 12, line 50-col. 13, line 22). RIBI specifically teaches that with regard to a B1 reductase protein, "Crystals were formed at the air-water interface" at column 10, line 25, thus claims 1, 5, 8, and 67 are anticipated. RIBI specifically teaches application of lateral pressure (col. 7, lines 31-37) and teaches that surfactants and polymers are not necessary to get ordered protein arrays (column 7,

lines 43-45), therefore the pressure applied is inherently above whatever critical density point is required for formation of a 2D or 3D ordered array, therefore claims 3, 64, 68, and 70 are anticipated.

Applicant's arguments filed 1/23/07 have been fully considered but they are not persuasive. The argument that RIBI teaches proteins bound to ligands in his surfactant layer is moot with regard to the instant claims as (1) the instant claims are directed to a method, not a product, and there is no limitation with regard to a final "structure" or product to be formed either before or after crystallization occurs and (2) the claims recite open claim language and therefore do not exclude addition of ligands, etc. nor do they exclude binding of the protein to a ligand, cofactor, lipid, or another protein. In fact, claims 5 and 70 specifically limit the contact of protein to an interface to be in the presence of lipids, and it is noted that all of RIBI's surfactant layers comprise lipids. In response to the argument that RIBI's layers are "synthesized" at a surfactant-aqueous interface, it is noted that RIBI specifically teaches that his protein crystals form at an air-aqueous interface, as set forth above. As RIBI teaches all the steps recited in the instant claims, as set forth above, the examiner maintains that the claims are anticipated, and maintains the rejection.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1631

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 6, 63, 69, and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over RIBI (US 4859538), as applied to claims 1, 3, 5, 8, 64, 67, 68, and 70 above, and further in view of OHLSSON et al. (Bioelectrochemistry and Bioenergetics (1995) vol. 38, pp. 137-148).

RIBI teaches a method of obtaining 2D and 3D ordered/crystalline structures of proteins wherein proteins and lipids are exposed to pressure at an air/liquid interface, as set forth above. RIBI specifically teaches crystallization of subunit B1 of a ribonucleoside reductase at an "air-water interface" in the presence of lipids, wherein surface pressure is applied to the air-water interface (col. 10, lines 7-31). RIBI further teaches that a variety of proteins, including membrane proteins may be crystallized in his method (col. 4, lines 51-62 and col. 8, lines 42-50). RIBI does not specifically teach use of proteoliposomes in his method.

OHLSSON teaches that cholera toxin may be bound to proteoliposomes on a surface, and will retain its activity when so bound (abstract).

It would have been obvious to one of ordinary skill in the art at the time of invention to have crystallized the membrane proteins of RIBI using the proteoliposomes of OHLSSON in the lipid layer in the method of RIBI where the motivation would have been to crystallize the proteins in the method of RIBI in an active conformation, as suggested by the teaching of OHLSSON that proteoliposomes aid in retaining biological activity of at least one membrane protein (abstract).

Applicant's arguments filed 1/23/07 have been fully considered but they are not persuasive. Applicant argues that OHLSSON does not overcome the argued deficiencies of RIBI. As the examiner maintains that RIBI teaches the limitations of claims 1, 3, 5, 8, 64, 67, 68, and 70, as set forth above, she also maintains that RIBI and OHLSSON make obvious the limitations of claims 4, 6, 63, 69, and 71.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie Moran whose telephone number is 571-272-0720. The examiner can normally be reached on M-F 6:30 am- 2 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marjorie Moran  
Primary Examiner  
Art Unit 1631

*Marjorie A. Moran*  
4/14/07